

2307U-107

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

In re application of)

Robert L. Lundak)

Serial No. 247,656)

Filed: March 26, 1981)

For: HIGH FUSION FREQUENCY)
FUSIBLE LYMPHOBLASTOID)
CELL LINE)

Examiner: J. Tarcza

Art Unit: 172

REQUEST FOR RECONSIDERATION
UNDER 37 C.F.R. §1.197(b)

#23
Reg. for
Recon

San Francisco, CA 94105

Commissioner of Patents and Trademarks

Washington, D.C. 20231

Sir:

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BOARD OF APPEALS

Applicant, by his attorney, respectfully requests reconsideration of the decision in the subject application affirming the Examiner's rejection of Claims 1 and 2 in the subject application. In the alternative, applicant respectfully requests that the decision be designated a new grounds of rejection as provided for under 37 C.F.R. §1.196(b). In addition, applicant respectfully requests that the accompanying declarations be considered by the Honorable Board or in the alternative be submitted to the Primary Examiner for his consideration as provided for under 37 C.F.R. 1.196(b).

1. The subject declarations are submitted at this late date because issues are raised by the decision of the Honorable Board which it is submitted were not in contention during prosecution. The first issue concerns the deposit for 20 years. As is evidenced by the accompanying exhibits and the declaration of Mrs. Bobbie A. Brandon of

the A.T.C.C., while the original deposit was for 20 years, at the time of the appeal to the Honorable Board, the deposit was under the Budapest Treaty requirements and was, therefore, for the 30 years indicated as reasonable under the Rule of Reason. The Honorable Board did not rule whether where there is a deposit of the organism, timely or not, subsequent changes in the conditions under which the deposit maintained are permissible and not considered as new matter.

2. Whether applicant had established by virtue of his declaration that the cell line had been maintained to ensure viability from the time of filing of the patent application to the time of deposit at the A.T.C.C. and whether in fact the cell line deposited at the A.T.C.C. is the subject matter of the application. This latter issue was designated as a §1.196(b) rejection in the concurring opinions.

3. The Honorable Board cites the Budapest Treaty and In re Glass in support of its decision finding that deposit of a biological must be made on or before the date of filing. It further states that such holding is not contrary to any statute or court decision and has not been shown to be unreasonable or unfair. It is submitted that this is an inadequate legal basis for its holding.

I. The Thirty-year Requirement

Applicant's attorney has carefully reviewed the Examiner's answer and final rejection and finds nothing in either document to suggest that the time period was in issue. Furthermore, the Honorable Board's attention is directed to applicant's amendment under Rule 116, filed

April 11, 1983, which included a copy of a letter received from the A.T.C.C. signed by Mrs. Bobbie A. Brandon stating that the period of maintenance would be for 30 years. It therefore comes as some surprise that the Honorable Board found as an additional basis for affirmation of the Examiner, that the subject cell line (accepting that the cell line WI-L2-729 HF₂ is the subject cell line) was maintained for the insufficient period of 20 years under a rule of reason first espoused in their decision in this case.

Applicant's attorney would note that when the issue of deposit became an important issue, it was then the conventional wisdom that 20 years would suffice. The fee for 20 years was less than the fee for 30 years, so there was an economic advantage. Secondly, since the pendency of a patent is 17 years prior to expiration and the normal pendency of prosecution is three years, 20 years seemed reasonable. Therefore, under the circumstances at the time of filing of the subject application, applicant and applicant's attorney believed that they were fulfilling under a rule of reason, the requirement of "permanence" set forth in MPEP 608.01(p)C. The conventional wisdom is now that 30 years is required and the Honorable Board appears to have confirmed that as reasonable.

The questions then devolves around whether applicant's change of the period of maintenance from 20 years to 30 years is impermissible new matter and cannot be considered as affecting the Honorable Board's decision. However, it is believed that the decision of Feldman v. Aunstrup, 186 USPQ 108 (CCPA 1975) is dispositive of the issue. As the Honorable Board is aware, Aunstrup deposited

his cell line in a foreign independent depository where the disposition of the cell line remained under his dominion and control. Only during the pendency of an interference, were the conditions under which the deposit was maintained changed to fulfill the then pertaining Argoudelis conditions (In re Argoudelis, 168 USPQ 99 (CCPA 1970)). Both the Honorable Board of Patent Interferences and the Appellate Court found that this was sufficient to fulfill the requirements of §112. It is therefore submitted that under the applicable law the subject cell line does fulfill the 30 year requirement and the Honorable Board is respectfully requested to withdraw the rejection. Failing this, the Honorable Board is earnestly requested to treat the rejection of 20 years as a 37 CFR §1.196(b) rejection and allow the Examiner to review the accompanying exhibits and documents for a determination of whether the subject cell line has fulfilled the 30 year requirement set forth by the Honorable Board.

II. Identity of the Cell Line

While the majority did not challenge whether the cell line which is the subject matter of the claims was in fact the cell line retained by the inventor's colleagues, was the cell line submitted to the A.T.C.C. and was the cell line that has been maintained at the A.T.C.C. since that time, nevertheless, in view of the concurring opinions, it would be considered to be an unreasonable burden on both the Honorable Board and the Court to appeal the present decision only to find that the Court agreed with one or both of the concurring opinions. Therefore, it is believe appropriate to submit to the Honorable Board at this time evidence which

removes the narrow technical basis for the concurrence in result of the concurring opinions.

One of the concurring opinions questioned the admissibility and evidence of the former declaration by Dr. Lundak. It is submitted that the former declaration was admissible, but could be challenged as to the weight of its evidence. The accompanying declaration by Dr. Lundak establishes that his statements as to the maintenance of the ampules by Drs. Lubin and Lewis were not hearsay, but were observations based on his own experience. Furthermore, declarations can be provided by Drs. Lubin and Lewis corroborating their maintenance of the cell line from at least March 26, 1981 to April 2, 1981 and thereafter.

Within the ability of applicants to establish the maintenance of the subject cell line, the transmission to the A.T.C.C. and the continued maintenance by the A.T.C.C. of the cell line received from Dr. Lundak, it is believed that applicant has fulfilled that burden. Short of having an independent authority compare the samples deposited with the A.T.C.C. and the samples maintained by Dr. Lundak to establish their identity, there is little more that applicant can do to establish the chain of possession. For the reasons given above, the Honorable Board is either requested to accept the declarations and make them part of the record as part of their determination on reconsideration or send the declarations to the Primary Examiner for his consideration.

III. A deposit is not required at the time of filing, but may be required at some future date.

Applicant's attorney will not repeat the arguments made in his original brief and reply brief, but incorporates these arguments by reference and supplements those arguments as follows. The majority has cited the Budapest Treaty of which the United States is a signatory as a basis for requiring deposit at the time of filing and maintenance of the deposit for 30 years. While the Honorable Board recognizes that the Budapest Treaty does not modify the requirements of Title 35, nevertheless it is their contention that the requirements for a depository for purposes of the Budapest treaty are the minimum requirements for a deposit under MPEP 608.01(p)C.

It should be noted that the Budapest Treaty sets up requirements for a depository, but does not set up requirements for an applicant. As stated in the memorandum by Commissioner Diamond published at 999 OG 2 on October 7, 1980, "Each such depository will be authorized to receive and store deposits, and dispense samples thereof, in compliance with the Treaty and the patent laws of each state adhering thereto" (emphasis added). Therefore, the requirements of the depository are minimum requirements which must be fulfilled by a depository, but an applicant is subject to the requirements of the law of the state of the Patent Office. The Budapest Treaty requirements are only relevant under a rule of reason to the extent that the patent laws of those states which have the same requirements for deposits as set forth for depositories are analogous to United States' law. For example, the Budapest Treaty provides for a determination of viability, while the

United States has not instituted such requirement. Germany is satisfied with a deposit for 20 years as distinct from the 30 years required under the European Patent Office and the Japanese Patent Office. There are additional considerations of the Budapest Treaty for which there are no rulings in the United States, such as interruption of viability and how this may be corrected.

The fact remains that there are a large number of considerations which due to the manner in which the rules concerning deposits arose in the United States, have not been resolved and leave applicants at risk. It is submitted that this present decision perpetuates uncertainties related to deposit, which create uncertainty in an area where certainty is desirable and can be provided either through legislation or if the Patent and Trademark Office has the authority by appropriate rule making.

There are a number of reasons why the present system is considered to be inappropriate. The first is that it is not clear in many situations whether or not a deposit should be required. Under the Honorable Board's present decision, the applicant is placed at risk in making the decision prior to any ruling on the part of the U.S. Patent and Trademark Office. Thus, in accordance with the present regulations, the applicant must deposit or run the risk that his application will be found to be a nullity and the applicant will have lost the protection of his filing date. On the other hand, if the applicant deposits the microorganism, but such deposit was unnecessary, the public obtains an unwarranted benefit in that the substantial technology involved in developing the organism, which may be ancillary to the invention, is disclosed to the public

For example, with many constructs it is desirable to have a marker which allows for selection of the organisms which have received the construct. In addition, the marker may provide for maintenance of the construct in the host. The marker may be unrelated to the invention, which may be expression or cloning of a particular gene. Unless the applicant is willing to carry out two different procedures, one with his desired marker and one with a conventional marker, the only construct available to the applicant for deposit will be the construct containing his proprietary marker. Under the present ruling, the applicant must forsake his proprietary property in order to protect the opportunity to obtain a patent on a different and unrelated DNA sequence which is the subject of his invention. It would seem more appropriate that the applicant should be allowed to raise the issue with the Primary Examiner and have the issue of the requirement of a deposit resolved prior to requiring the deposit.

The next consideration is the best mode. The situation with fusion partners is exemplary. For example, one may find a new procedure for preparing a unique fusion partner. Based on the preliminary data, it may be established that a number of the fusion products have superior properties. An application may be filed, but as research continues one of the sister clones is found to be far superior to the original clones which were screened. It would seem in the interest of the public that the best clone be deposited, which would not be new matter, since it existed at the time of the filing date and, furthermore, would have been prepared by the procedure described in the application. In any event, the applicant should be allowed

the selection between the clones which have been screened at the time of filing, or subsequent clones which existed at that time and have proven to be of superior merit.

The above situations are raised as exemplary of situations which applicant's attorney has in fact faced and it is submitted are clearly not exhaustive of numerous situations, where it would be in the interest of the public and the applicant to allow for deposit after prosecution and at the time of allowance.

So far as reliance on In re Glass, 181 USPQ 31 (CCPA 1974), applicant's attorney adopts the analysis of the concurring opinions in that Glass is not relevant, since it is directed to a different issue and does not concern the present situation. There is some irony in the Boards's having referred to a "constructive reduction to practice," when a deposit requires that there be an actual reduction to practice. As stated in that decision, In re Glass, 181 USPQ 31, 34,

It is an applicant's obligation to supply enabling disclosure without reliance on what others may publish after he has filed an application on what is supposed to be a completed invention. If he cannot supply enabling information, he is not yet in the position to file.

Clearly, that is not the situation in the present case, where the record is not challenged by the majority that it shows that applicant was in a position to provide enabling disclosure, having described the method of preparation of the cell line and, furthermore, having his cell line in his possession and under conditions whereby permanency and viability during the period of prosecution would be maintained.

For the reasons given above, the Honorable Board is respectfully requested to reconsider their decision and reverse the Examiner; or in the alternative enter the accompanying exhibits and declarations and rule on their relevance; or in the alternative modify their decision at least as to the 20 year deposit; or in the alternative find that the rejection for the 20 year period was a new rejection and the application should be returned to the Primary Examiner in light of the accompanying declarations and exhibits for review by the Primary Examiner.

Because this decision is of great moment and importance to the patent bar as well as the Patent and Trademark Office in its examination of applications, it is respectfully requested and solicited that the review of this request for reconsideration be expedited in whatever manner the Honorable Board may find expedient. Applicant's attorney takes this opportunity to thank the Honorable Board for its cooperation in this matter.

Respectfully submitted,
TOWNSEND and TOWNSEND

Date

9/10/84

By

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BIR/gs

Enclosures

1. Declaration of Lundak
2. Declaration of Brandon
3. BIR ltr to ATCC, 2/24/82
4. ATCC ltr to BIR, 3/2/82